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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,088	01/18/2007	Zoran Gojkovic	GOJKOVIC3	7165

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EXAMINER	
KOSSON, ROSANNE	

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,088	GOJKOVIC, ZORAN	
	Examiner	Art Unit	
	Rosanne Kosson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7,9-22,27-43,46-50,55,57-59,61,63,64,69-72 and 76* is/are pending in the application.

4a) Of the above claim(s) *10-15,30,46 and 47* is/are withdrawn from consideration.

5)☒ Claim(s) *1,2,4,5,7,9,16-22,55,57-59,61,63,64,69-72 and 76* is/are allowed.

6)☒ Claim(s) *36-43 and 48-50* is/are rejected.

7)☒ Claim(s) *27-29 and 31-35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/21/09*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The amendment filed on July 21, 2009 has been received and entered. Claims 1, 7, 29-32, 48 and 55 have been amended. Claims 3, 6, 8, 23-26, 44-45, 51-54, 56, 60, 65-68 and 73-75 have been canceled. No claims have been added. As discussed in the previous Office actions, claims 10-15, 30, 46 and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions (polypeptides and methods of using them). These claims remain withdrawn. In view of Applicant's amendments to the claims of the elected invention, however, claims 1, 2, 4, 5, 7, 9, 16, 19, 20, 22, 55, 57-59, 61, 63, 64, 69-72 and 76, drawn to polynucleotides encoding a polypeptide having 90% sequence identity to SEQ ID NO:2 and deoxyribonucleoside kinase activity, are considered to be allowable, pending the results of an allowance conference. As a result, certain method claims have been considered for rejoinder under the doctrine of In re: Ochiai, claims 33-43 and 48-50. Previously withdrawn claims 17, 18 and 21, claims drawn to non-elected species, are rejoined. Previously withdrawn claims 27-29, 31 and 32, claims originally drawn to different products, are rejoined, because they have been amended to recite a composition comprising the polynucleotide of claim 1 (or the polynucleotide in a host cell) and a nucleoside analogue. Accordingly, claims 1, 2, 4, 5, 7, 9, 16-22, 27-29, 31-43, 48-50, 55, 57-59, 61, 63, 64, 69-72 and 76 are examined on the merits herewith.

In his response, Applicant asserts that all of the different inventions should be rejoined. Applicant cites MPEP § 821.04, related to the concept of rejoinder, and two paragraphs in Annex B of the PCT administrative instructions, one related to unity of invention and one related to independent and dependent claims. In reply, Applicant has elected as his invention a product

invention, the product claims drawn to the polynucleotide of SEQ ID NO:1, Group 1. Under the concept of unity of invention, should there be unity of invention, Applicant is entitled to examination of the first named method of making the product and the first named method of using the product. See 37 CFR 1.475(b) – (d), as discussed in the previous Office actions. The instant application has no claims for making the elected invention. Under the doctrine of In re: Ochiai, as previously discussed, should the elected polynucleotide claims be found to be allowable, Applicant is entitled to rejoinder of method claims that are not broader in scope than the allowable product claims. Also required for rejoinder is that these methods satisfy the requirements for written description, enablement, and clear and definite claim language. The claims that are eligible for rejoinder or considered for rejoinder are indicated above and discussed below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

In view of Applicant's amendments to the claims, the objections in the previous Office action are replaced with the following objections. Claims 7, 27-29, 31, 32, 33-35 and 48-50 are objected to because of the following informalities. Appropriate correction is required.

In claim 7, the term "sequence presented of SEQ ID NO:1" should be changed to "sequence of SEQ ID NO:1."

In claims 27-29, 31 and 32, the term "article" should be replaced with the term "composition." The claims should recite a composition comprising, e.g., the polynucleotide of SEQ ID NO:1 and a nucleoside analogue. An article implies industrial manufacture (an article of manufacture made by one or more machines). Pharmaceutical products are compositions.

Claims 33 and 48 and their dependent claims recite the step of transfecting or transducing a cell or a subject with the polynucleotide of claim 1. Cells may be transfected or transformed with exogenous vectors, but not transduced. The term "transducing" should be deleted.

Also, claim 33 recites a "nucleoside analogue prodrug" in the preamble and in the steps but recites "a (cytotoxic) drug" in the "wherein" clause. Parentheses are not permitted in the claims, and all the parts of the claim should match. The "wherein" clause should be amended to recite a nucleoside analogue drug.

Claims 28, 35 and 43 recite the term "AraC." The name of this compound should be written out in full, followed by the abbreviation in parentheses if desired, so that the meaning of the claims is clear and apparent to the reader.

Claim Rejections - 35 USC § 112, first paragraph, Enablement

Claims 36-43 and 48-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims are drawn to gene therapy methods of treating cells and subjects, including humans (see pp. 13, 15 and 16). In the method of claim 36, an animal subject is treated with a polynucleotide encoding a polypeptide having 90% sequence identity to SEQ ID NO:2 (the polynucleotide of claim 1). This treatment is claimed to inhibit any pathogenic agent, i.e., any microorganism, any tumor cell or any immune cell. In claim 48, the transgenic expression of the polypeptide encoded by the polynucleotide of claim 1 is imaged in a nuclear imaging technique in which any substrate is changed to "said prodrug."

The factors to be considered in determining whether or not undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir.1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the relative skill of those in the art, (5) the predictability or unpredictability of the art, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In Wands, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in

successfully obtaining the claimed invention. (Wands, 8 USPQ2d 1406). Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of Wands factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

Factors pertinent to this discussion include the predictability of the art, guidance in the specification, the breadth of claims and the amount of experimentation that would be necessary to use the invention.

Regarding the breadth of the claims, the claims are very broad, because they recite that any "pathogenic agent" may be inhibited by administering to an animal a polynucleotide encoding a polypeptide having 90% sequence identity to SEQ ID NO:2. They also recite that transgenic expression of a protein may be imaged in a nuclear imaging technique by transfecting a subject (or a cell) with a polynucleotide encoding a polypeptide having 90% sequence identity to SEQ ID NO:2 and administering to the subject or cell any substrate. In this method, something changes into a prodrug.

Regarding the guidance in the specification, the specification repeats what is recited in the claims. But, the specification provides no additional information, no working examples, no prophetic examples, no outlines of experimental protocols or a rational and predictable scheme as to how these methods are carried out. Thus, one of skill in the art would have to search for or generate the required guidance entirely on his own. No specific gene therapy methods for inhibiting a pathogenic agent are disclosed. No specific gene therapy methods for imaging transgenic protein expression are disclosed.

Without sufficient guidance for the claimed methods, which has not been provided,

obtaining the results that the claimed methods can be practiced is unpredictable, and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. Applicants have not provided sufficient guidance to enable one of skill in the art to make and use the invention as recited in the claims.

In view of the foregoing, the claims fail to satisfy the enablement requirement.

Claim Rejections - 35 USC § 112, second paragraph

In view of Applicant's amendments to the claims (canceling the rejected claims), the rejections in the previous Office action are withdrawn and replaced with the rejection below.

Claims 33-35 and 48-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33-35 are confusing, because they recite a method of sensitizing a cell to a prodrug by transfecting the cell with a polynucleotide encoding a deoxyribonucleoside kinase and delivering the prodrug to the cell. If the transfected cell expresses the exogenous gene and encoded enzyme, it will phosphorylate the prodrug to the drug, which appears to be more toxic to the cell than the prodrug. But, this method is one of killing or damaging a cell with a drug. The sensitivity of the cell to the prodrug does not change. Appropriate correction is required.

Claim 48 recites the limitation "said prodrug" in step (iii). There is insufficient antecedent basis for this limitation in the claim. The preamble and the first two steps recite a method of converting a substrate to a substrate-monophosphate. It is unclear and confusing how either the substrate or the product is changed to a prodrug or said prodrug (which prodrug?). Appropriate correction is required.

As discussed above, the claims that are objected to but not rejected (claims 7, 27-29, 31 and 32) will be considered for rejoinder and allowance pending the results of an allowance conference.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652
rk/2009-07-28

/Karen Cochrane Carlson/

Primary Examiner, Art Unit 1656